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PROGRAMS OFFICE

FAX

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Camilla C. Williams

FROM

26

PAGES (WITH COVER)

2282

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40198/181160

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COMMENTS

Mr. Bell - Thank you for your assistance. Attached is
a copy of the IPER.

Kind regards.

Camilla Williams

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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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1100 Peachtree Street
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ATLANTA, Georgia 30309-4530
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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

06. 08. 01

Applicant's or agent's file reference
CAN100PCT

IMPORTANT NOTIFICATION

International application No.
PCT/IB00/00426

International filing date (day/month/year)
07/04/2000

Priority date (day/month/year)
09/04/1999

Applicant
CANICA DESIGN INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CAN100PCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB00/00426	International filing date (day/month/year) 07/04/2000	Priority date (day/month/year) 09/04/1999	
International Patent Classification (IPC) or national classification and IPC A61B17/32			
Applicant CANICA DESIGN INC. et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 5 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 06/11/2000		Date of completion of this report 06. 08. 01	
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Koch, J-M Telephone No. +49 89 2399 2979	



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB00/00426

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*)
- Description, pages:**

1-7 as originally filed

Claims, No.:

1-43 as received on 19/04/2001 with letter of 19/04/2001

Drawings, sheets:

1/8-8/8 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB00/00426

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Yes:	Claims	1-20,23-43
	No:	Claims	21,22
Inventive step (IS)	Yes:	Claims	1-20,23-43
	No:	Claims	21,22

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Industrial applicability (IA) Yes: Claims 1-43
 No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB00/00426

SECTION IV:

The separate inventions are:

1. A handle assembly (see claim 1) comprising a blade bar urging the distal end of the blade into engagement with the handle body.
2. A handle assembly (see claim 21) comprising a blade bar having a tang for insertion in a keyed slot, and a spring for urging the blade bar into the handle body.
3. A handle assembly (see claim 23) comprising a blade bar having a tang for insertion in a keyed slot, a spring for urging the blade bar into the handle body, and a collet.
4. A handle assembly (see claim 29) comprising a blade bar urging the blade into engagement with the handle body, and a collet having a through bore within which the blade bar is disposed.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

- A. A handle assembly for a detachable scalpel blade having a keyed slot. the handle assembly comprising: a handle body having a longitudinal axis, and a blade bar having a portion protruding from the handle body for engaging the blade (resp. for insertion in the keyed slot), is known from the document D1 (= DE-B-1144437) (see figures 1-2).
- B. A handle assembly according to point 1. does not necessarily comprise a tang and a spring according to point 2., and inversely.
- C. A handle assembly according to point 1. does not necessarily comprise a tang, a spring and a collet according to point 3., and inversely.
- D. A handle assembly according to point 1. does not necessarily comprise a collet having a through bore within which the blade bar is disposed according to point 4., and inversely.
- E. A handle assembly according to point 2. does not necessarily comprise a collet according to point 3., and inversely.
- F. A handle assembly according to point 2. does not necessarily comprise a blade bar urging the blade into engagement with the handle body and a collet having a through bore within which the blade bar is disposed according to point 4., and inversely.
- G. A handle assembly according to point 3. does not necessarily comprise a blade bar urging the blade into engagement with the handle body and a collet having necessarily a through bore within which the blade bar is disposed according to point 4., and inversely.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB00/00426

SECTION V:

A. Claims 1-20 and 23-43:

State of the art:

The state of the art is given by document D1 (see Section IV Point A.).

Object of the invention:

The object of the invention is to provide a scalpel assembly that allows release of a blade without requiring medical personnel to touch the blade; that allows release of the blade by manipulation with one hand; that allows easy installation; that is durable and capable of withstanding repeated sterilization; and with desirable ergonomic properties.

Solution:

Especially a handle assembly comprising a blade bar urging the distal end of the blade into engagement with the handle body (see claim 1); comprising a collet (see claim 23); or comprising a collet having a through bore within which the blade bar is disposed (see claim 29); is neither disclosed nor suggested in the state of the art.

B. Claims 21 and 22:

Novelty:

The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 21 and 22 is not new in respect of prior art defined in the regulations (Rule 64(1)-(3) PCT).

1. Claim 21:

Document D1 (= DE-B-1144437), which is considered to represent the most relevant state of the art, discloses a handle assembly having all features of independent claim 21.

INTERNATIONAL PRELIMINARY

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EXAMINATION REPORT - SEPARATE SHEET

In fact, document D1 discloses a handle assembly (see figures) for a detachable scalpel blade (2) (see column 1, lines 1-6) having a keyed slot (see figure 1), the handle assembly comprising: (a) a handle body (1) having a longitudinal axis (see figure 1), (b) protruding from the handle body (1) a blade bar (7) (see column 3, lines 56-60) having a tang (see figure 2) for insertion in the keyed slot (see column 3, lines 60-64; column 4, lines 19-24; figure 2), and (c) a spring (6) for urging the blade bar (7) into the handle body (1) (see column 4, lines 56-62).

2. Claim 22:

Document D1 also discloses all features of dependent claim 22 (see groove (30), heel (17)).

SECTION VII:**1. Claims:**

- 1.1 The independent claims have not been properly cast out in the two-part form, with those features which in combination are part of the prior art (see document D1) being placed into the preamble. They, therefore, do not meet the requirements of Rule 6.3(b) PCT.
- 1.2 Reference signs in parentheses should have been inserted in the claims to increase their intelligibility; Rule 6.2(b) PCT. This applies to both the preamble and the characterising portion.

2. Description:

- 2.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein (in a purely factual manner (see PCT-Guidelines Chapter II 4.4)).
- 2.2 The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

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2.3 The units at page 7, lines 9-10 are not SI units.

2.4 The reference signs (25, 27, 90, 101) (see figures) are not used in the description.

SECTION VIII:

1. The passage of the description at page 1, lines 4-6 is not acceptable (see PCT-Guidelines Chapter II 4.17).
2. The term "slot", used in claims 25-27, is not clear (Article 6 PCT).
In fact, the collet comprises a slit.

Claims:

1. A handle assembly for a detachable scalpel blade having a keyed slot, the handle assembly comprising:
 - (a) a handle body having a longitudinal axis, and
 - (b) a blade bar having a portion protruding from the handle body for engaging the blade and urging the distal end of the blade into engagement with the handle body.
2. The assembly of claim 1, further comprising a spring for urging the bar.
3. The assembly of claim 1, wherein the blade is received in a groove in the protruding portion of the bar.
4. The assembly of claim 2, wherein the spring comprises a tapered, coiled spring.
5. The assembly of claim 3, wherein the bar is bent and the groove is approximately parallel to the longitudinal axis.
6. The assembly of claim 1, further comprising a collet having a through bore within which the blade bar is disposed.
7. The assembly of claim 6, wherein the collet has a slit within which an end of the blade is received.
8. The assembly of claim 6, wherein the collet has at least one sloping face for guiding the blade into the slit.
9. The assembly of claim 6, wherein the collet has a pair of faces sloping toward the slit for guiding the blade end into the slit.
10. The assembly of claim 6, wherein the bore is sized and shaped to permit the bar to move laterally along one axis orthogonal to the longitudinal axis.
11. The assembly of claim 6, wherein the bore has a generally oval cross-sectional shape so that the bar can move laterally within the bore along one axis orthogonal to the longitudinal axis.

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12. The assembly of claim 1, wherein the bar is coupled to an actuator for urging the protruding portion of the bar out of the handle assembly for removing the blade from the bar or mounting the blade on the bar.
13. The assembly of claim 12, wherein the actuator is a button attached to a rod attached to the bar.
14. The assembly of claim 13, wherein the rod has two ends and the bar attaches to one end and the button attaches to the other end.
15. The assembly of claim 1, wherein the handle body further comprises:
(a) a handle grip,
(b) a collet having a proximal end, and
(c) a collet core.
16. The assembly of claim 15, wherein the handle grip has a generally oval cross-sectional shape.
17. The assembly of claim 15, wherein the handle grip further comprises ribs.
18. The assembly of claim 15, wherein the collet flares at its proximal end.
19. The assembly of claim 1, further comprising a retainer for capturing the rod within the handle body.
20. The assembly of claim 19, wherein the retainer is attached to the handle body with mating threads.
21. A handle assembly for a detachable scalpel blade having a keyed slot, the handle assembly comprising:
(a) a handle body having a longitudinal axis,
(b) protruding from the handle body a blade bar having a tang for insertion in the keyed slot, and
(c) a spring for urging the blade bar into the handle body.

22. The assembly of claim 21, wherein the tang is defined by a groove and a heel.

23. A handle assembly for a detachable scalpel blade having a keyed slot, the handle assembly comprising:

- (a) a handle body having a longitudinal axis,
- (b) protruding from the handle body a blade bar having a tang for insertion in the keyed slot,
- (c) a spring for urging the blade bar into the handle body, and
- (d) a collet.

24. The assembly of claim 23, wherein the collet further comprises a through bore within which the blade bar is positioned.

25. The assembly of claim 24, wherein the collet further comprises a slot.

26. The assembly of claim 25, wherein the collet further comprises at least one face sloping toward the slot.

27. The assembly of claim 26, wherein the at least one sloping face guides the blade end into the slot thereby preventing the blade from disengaging from the heel.

28. The assembly of claim 23, wherein the tang is defined by a groove and a heel.

29. A handle assembly for a detachable scalpel blade having a keyed slot, the handle assembly comprising:

- (a) a handle body having a longitudinal axis,
- (b) a blade bar having a portion protruding from the handle body for engaging the blade and urging the blade into engagement with the handle body, and
- (c) a collet having a through bore within which the blade bar is disposed.

30. The assembly of claim 29, wherein the blade is received in a groove in the protruding portion of the bar.

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31. The assembly of claim 30, wherein the bar is bent and the groove is approximately parallel to the longitudinal axis.
32. The assembly of claim 29, wherein the collet has a slit within which an end of the blade is received.
33. The assembly of claim 29, wherein the collet has at least one sloping face for guiding the blade into the slit.
34. The assembly of claim 29, wherein the collet has a pair of faces sloping toward the slit for guiding the blade end into the slit.
35. The assembly of claim 29, wherein the bore is sized and shaped to permit the bar to move laterally along one axis orthogonal to the longitudinal axis.
36. The assembly of claim 29, wherein the bore has a generally oval cross-sectional shape so that the bar can move laterally within the bore along one axis orthogonal to the longitudinal axis.
37. The assembly of claim 29, wherein the bar is coupled to an actuator for urging the protruding portion of the bar out of the handle assembly for removing the blade from the bar or mounting the blade on the bar.
38. The assembly of claim 37, wherein the actuator is a button attached to a rod attached to the bar.
39. The assembly of claim 38, wherein the rod has two ends and the bar attaches to one end and the button attaches to the other end.
40. The assembly of claim 29, wherein the handle body further comprises:
(a) a handle grip,
(b) a collet having a proximal end, and
(c) a collet core.
41. The assembly of claim 40, wherein the collet flares at its proximal end.

42. The assembly of claim 29, further comprising a retainer for capturing the rod within the handle body.

43. The assembly of claim 42, wherein the retainer is attached to the handle body with mating threads.